

REMARKS

Claims 16-18 have been cancelled without prejudice in view of the Restriction Requirement made final by the Patent Office.

Claims 12-15 are now pending.

Claim 12 has been amended to remove the objections raised in the Office Action and also to obviate the rejection under 35 U.S.C. §112, first paragraph. The amended claim corresponds to the Examiner's suggested amendment thereof.

Reconsideration is respectfully requested of the rejection of the pending claims under 35 U.S.C. §102(b) as allegedly anticipated by Spencer, et al. (WO 98/42361).

The Spencer reference WO 98/42361 corresponds to U.S. Patent 5,916,569 which reference has been used in referring to Spencer with regard to the Office Action.

In order to anticipate, it is well-established law that each and every element of the claimed invention must be described in a single reference.

The teaching of Spencer is limited to administration of GH to treat or prevent erectile dysfunction due to damage to parasympathetic nerves that regulate the erectile function (col. 3, lines 30-34). This damage may be the result of various surgical treatments or other conditions known to adversely affect parasympathetic nerves such as diabetes, aging, or alcoholism (col. 3, lines 25-29). All data collected and presented by Spencer discuss surgical damage to a rodent model and subsequent treatment with GH to improve the number of parasympathetic nerves and erectile function (col. 4, lines 25-31). The limit of Spencer's disclosure to neurogenic erectile dysfunction precludes a finding of anticipation, as that element is not an aspect of the claim.

The Examiner further indicates that while Spencer does not specifically mention administration to a growth hormone deficient patient, Spencer discloses administration of hGH for a disorder as a result of aging.

Spencer discloses the treatment of a patient for parasympathetic nerve damage as a result of aging (col. 3, lines 25-29) among other etiologies. However, there is no indication that the nerve damage is a result of either an hGH deficiency or due to an insufficient increase in hGH concentration during sexual stimulation. The disorders Spencer describes as able to be treated by GH are unrelated to both hGH deficiency and an insufficient increase in hGH concentration during sexual stimulation. Spencer indicates “the invention solves the problem of impotence secondary to pelvic surgery, pelvic injury, alcoholism, diabetes mellitus, aging, or any condition that irreversibly damages the penile nerves.” (col. 4, lines 18-21). Spencer provides no disclosure indicating that the nerve damage experienced by the aging patient is due to either an hGH deficiency or an insufficient increase in hGH concentration during sexual stimulation.

Claim 12 as presently amended recites the element: “wherein insufficient increase in hGH concentration occurs during sexual stimulation or a hGH deficiency exists.” Spencer does not disclose either aspect of this claim element; Spencer discloses only neurogenic erectile dysfunction. Therefore, Spencer does not anticipate claim 12 and its dependent claims under the all elements rule.

Spencer and the instant application also disclose mechanisms of action that further differentiate the claimed matter and the reference. Spencer discloses the treatment of damaged nerves as the solution to the erectile dysfunction problem. Applicant indicates one use of GH treatment to activate the NO-cGMP pathway, leading to relaxation of the corpora cavernosa,

resulting in penile erection. These mechanistic differences further demonstrate the narrow nature of the Spencer disclosure and its inability to anticipate the claims of the instant patent.

In view of the above, Spencer does not teach each and every element of the claimed invention and therefore does not anticipate the pending claims. The Examiner's rejection should be withdrawn.

Favorable consideration of the amendment and allowance of the claims are earnestly solicited.

Respectfully submitted,

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